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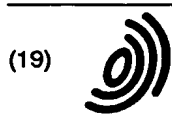
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(19)

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(11)

EP 0 714 668 A1

(12)

## EUROPEAN PATENT APPLICATION

(43) Date of publication:  
05.06.1996 Bulletin 1996/23

(21) Application number: 95114362.7

(22) Date of filing: 13.09.1995

(51) Int. Cl.<sup>6</sup>: **A61M 1/14**, A61K 9/08,  
A61K 9/14, B01F 1/00,  
A61L 2/04

(84) Designated Contracting States:  
AT BE CH DE DK ES FR GB IE IT LI NL PT SE

(30) Priority: 20.09.1994 SE 9403142

(71) Applicant: GAMBRO AB  
S-220 10 Lund (SE)

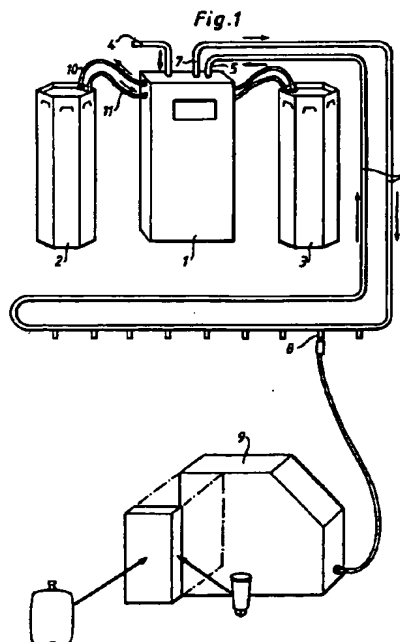
(72) Inventors:  
• Hallberg, Birger  
S-237 00 Bjärred (SE)  
• Jönsson, Lennart  
S-244 66 Furulund (SE)

• Jönsson, Sven  
S-245 44 Staffanstorp (SE)  
• Knutsson, Stefan  
S-237 00 Bjärred (SE)  
• Olsson, Lennart  
S-234 33 Lomma (SE)

(74) Representative: Asketorp, Göran  
Gambro AB  
Patent Department  
Box 10101  
220 10 Lund (SE)

(54) **Method and arrangement for centrally preparing a salt concentrate, a method for disinfecting the arrangement and a vessel intended for the arrangement**

(57) Arrangement and method for centrally preparing and distributing substantially saturated concentrate solution of common salt in water for preparation of a medical solution starting from a concentrate solution, for example dialysis solution and/or replacement solution for haemodialysis, haemofiltration or haemodiafiltration, as well as a method for disinfecting the arrangement, and a container intended for the arrangement. The arrangement consists of a concentrate generator (1) equipped with an inlet (4) for purified water and a distribution conduit (6) for distribution of the concentrate to concentrate connectors (8) and further to a dialysis machine (9). Several containers (2, 3) for common salt in particle form are connected to the concentrate generator via a conduit (10) for supply of water to the container and a conduit (11) for feeding the concentrate to the distribution conduit (6). By partial dissolution of the common salt in the water in the container, a substantially saturated concentrate solution is continuously formed. The container contains common salt in a quantity of, for example, 65 kg.



EP 0 714 668 A1

## Description

### TECHNICAL FIELD

The present invention relates to a method and an arrangement for preparing solutions for medical purposes, particular dialysis solutions and/or replacement solutions for use in haemodialysis, haemodiafiltration or haemofiltration, as well as other liquids for medical use, such as infusion solutions, peritoneal dialysis solutions, nutritional solutions, etc. In addition, the invention relates to a method for disinfecting such an arrangement and a vessel intended for the arrangement.

### BACKGROUND OF THE INVENTION

In a dialysis clinic for haemodialysis, a large number of patients are treated simultaneously, with each patient being connected to a dialysis machine, a so-called monitor, which prepares a dialysis solution and administers the solution to a dialyser which is connected to the patient.

In a monitor which is presently used, such as GAM-BRO AK-100, the preparation of the dialysis solution normally takes place by mixing two dialysis concentrates to a desired composition and concentration.

The dialysis concentrate can be an A-concentrate which consists of acetic acid, sodium chloride, potassium chloride, calcium chloride and magnesium chloride, and a B-concentrate consisting of bicarbonate. Reference is made to EP-B1-0 278 100 for further details.

These concentrates are diluted with water which is normally obtained from a particular water outlet at each treatment location. The water must be specially treated so that it contains as few impurities as possible and is normally prepared by the so-called RO process (reverse osmosis). Such a process is described in, for example, EP-B1-0 058 303 and EP-B1 0 058 304.

Usually, the water is purified centrally and is conducted to each patient location in a particular conduit system which is constructed with the intention to reduce the possibilities of bacteria contamination. Furthermore, the conduit system is regularly disinfected by feeding warm water at a temperature above 90°C through the system.

DE-A1-34 43 911 describes a method and an arrangement for batchwise preparation of a dialysis solution consisting of common salt, magnesium, calcium, potassium and glucose by mixing with so-called "zero-conductivity water", i.e. purified water, in a large tank. The prepared dialysis solution is then drained into containers of about 10 litres and placed at the dialysis clinic's disposal to form the above-mentioned A-concentrate after the addition of acid (which can take place in the monitor). The disadvantage with this process is that heavy containers with concentrate must be man-handled by the personnel and transported or carried to each patient location.

DE-C2-42 03 905 describes the distribution of a centrally prepared dialysis solution via a conduit system. The disadvantage with such a central distribution of dialysis solution is that the dialysis solution is a very good nutritional medium for many bacteria. According to DE-C2-42 03 905, a sterile filter is employed, though this does become expensive. Furthermore, very effective disinfection of the conduit system is required. The conduits must first be rinsed clean to remove the dialysis solution, after which hot water or other disinfecting agents are allowed to circulate in the conduits.

### SUMMARY OF THE INVENTION

Starting from the above-described state of the art, the present invention has as an object to propose a practical useful method and arrangement for centrally preparing solutions or concentrates intended for dialysis or other similar medical purposes.

A saturated concentrate solution of sodium chloride, common salt, is a very poor nutritional medium for bacteria and only a small number of bacteria are known which can survive in such an environment, so-called halo bacteria.

In addition, a saturated common salt solution may be heated to high temperatures without its properties or solubility being altered.

It has also been shown to be possible to continuously prepare a saturated common salt solution starting from a large quantity of common salt in powder form by means of passing water through the quantity of powder. If the grain size of the common salt crystals lies within a predetermined range, no formation of lumps of common salt occurs even with very large quantities of salt, something which otherwise could be expected (see EP-B1-0 278 100).

Thus, in accordance with the present invention there is provided a method for centrally preparing and distributing a concentrate of substantially only one salt in water for preparation of a medical solution starting from the concentrate, for example dialysis solution and/or replacement solution for haemodialysis, haemofiltration or haemodiafiltration, including: supplying primarily water to a container containing the salt at least partially in solid form; removing substantially saturated concentrate of the salt in water from the container; and distributing the concentrate to a distribution conduit and concentrate connectors arranged thereon, for preparation of the medical solution. The concentrate and/or water may be heated to a high temperature for distribution of the concentrate at said temperature to the distribution conduit. It is also possible to add a substance such as acetic acid to the concentrate or the water.

In an alternative embodiment, the concentrate is diluted to a suitable concentration for the dialysis solution, and possibly carbon dioxide gas is added before the distribution to the distribution conduit.

Moreover, there is provided, according to the invention, an arrangement for carrying out the abovementioned

tioned method for centrally preparing and distributing a concentrate of substantially only one salt in water, for preparing a medical solution starting from the concentrate, for example dialysis solution and/or replacement solution for haemodialysis, haemofiltration or haemodiafiltration, comprising a concentrate generator provided with an inlet for purified water and at least one distribution conduit for distribution of the concentrate to at least one concentrate connector, and further comprising at least one container for said salt which is at least partially in solid form; a conduit for supplying primarily water to the container to form a substantially saturated concentrate of the salt in water in the container by partial dissolving of the salt in the water; and a conduit for feeding the concentrate to the distribution conduit. It is convenient if the container contains the salt in a quantity of at least 10 kg, preferably more than 20 kg and most preferably more than 40 kg. Preferably, the salt is sodium chloride in particle form, which particles have a size between about 50 and 200  $\mu\text{m}$ .

In a preferred embodiment of the invention, the concentrate generator includes: a water tank to which primarily water is fed via an inlet; a conduit for supplying water from the water tank to one of the containers; a return conduit for returning substantially saturated concentrate from the container to the concentrate generator; and a pump for feeding the concentrate solution to the distribution conduit. Furthermore, a pressure meter is arranged in association with the inlet to the pump to detect a pressure downstream of the container, and a concentration meter adapted to measure the concentration of the salt in the concentrate before it is fed to the distribution conduit, and a valve for directing the concentrate to a drain should an error arise.

The invention also relates to a method for disinfecting the above-identified arrangement, intended for central preparation and distribution of a concentrate of substantially one salt in water, and consisting of a concentrate generator and at least one distribution conduit for distribution of the concentrate to at least one concentrate connector, wherein the concentrate is recirculated in a recirculation circuit comprising at least the distribution conduit, and in that the concentrate is heated to a high temperature, and possibly at an overpressure, to attain disinfection of the recirculation circuit.

Finally, the invention also comprises a container intended for the above-mentioned arrangement and containing sodium chloride in particle form in a quantity of at least 10 kg, preferably more than 20 kg and most preferably more than 40 kg, and being provided with an inlet for water and an outlet for concentrate, which inlet and outlets preferably have different connecting means, for example of male and female type.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be described in the following in greater detail by way of reference to preferred embodi-

ments of the invention and with reference to the attached drawings.

Fig. 1 is a schematic diagram, partially in perspective, of a first embodiment of the present invention.

Fig. 2 is a more detailed schematic diagram of a somewhat modified embodiment of the invention.

Fig. 3 is a perspective view of an inner bag intended to contain common salt and intended for use according to the invention.

Fig. 4 is a perspective view of a container provided with an inner bag according to Fig. 3.

Fig. 5 is a plan view of a blank which is intended to form the container according to Fig. 4.

Fig. 6 is a perspective view of the container without the inner bag.

#### DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

A first embodiment of the present invention is shown in Fig. 1. The arrangement according to the invention comprises a concentrate generator 1 with two salt containers 2, 3 for e.g. sodium chloride, NaCl, in powder form connected thereto. In addition, a water inlet 4 and a concentrate outlet 5 (preferably substantially saturated concentrated sodium chloride solution) are provided. The invention can be used with other salts or electrolytes, but for the sake of simplicity it will be described in the following when used with NaCl, common salt.

In addition, a distribution conduit 6 for the concentrate is provided which is preferably arranged in the form of a closed loop connected between the concentrate outlet 5 and a return inlet 7 on the concentrate generator 1.

The distribution conduit 6 is provided with a plurality of concentrate connectors 8 to which one or more dialysis machines 9 for preparing and administering a dialysis solution are connected. In principle, any type of dialysis machine can be connected, though the dialysis machine should of course be adapted, and provided with an inlet, for substantially saturated NaCl solution.

By way of example, one such dialysis machine is GAMBRO AK-100, the construction of which is apparent from, for example, EP-B1-0 278 100. This dialysis machine prepares a ready-to-use dialysis solution starting out from a dry powder (such as bicarbonate powder) and other concentrate with predetermined compositions. A further example is apparent from EP-A1-0 443 324. In the dialysis machine according to any one of these documents, the particular preparation of NaCl concentrate is replaced by the connection to the concentrate connector 8 according to the present invention.

Each salt container 2, 3 is connected to the concentrate generator 1 via two conduits 10, 11. The conduit 10 supplies water to the upper region of the container and the conduit 11 returns saturated concentrate of NaCl solution from the lower region of the container. The concentrate is thereafter fed to the distribution conduit 6 via the outlet 5 which is shown in greater detail in Fig. 2. Of course, the feeding can take place in the lower region of

the container and the removal in the upper region if so desired. Other variations are also possible.

The principle behind the arrangement according to the invention is shown in more detail in Fig. 2. The same figure reference numerals as in Fig. 1 have been used for the same components.

As is apparent from Fig. 2, water enters the concentrate generator 1 via an inlet 4 to a water tank 20. The water level in the tank 20 is controlled by a level sensor 21 which controls an inlet valve 22. The tank 20 can include a heat source 23 for heating the water and/or regulating the water temperature via a temperature sensor.

The incoming water should be purified in a suitable manner, for example using filters of various types (ion exchange filters) and reverse-osmosis processes. The water is thus free from impurities such as salts, particles and bacteria.

The water is conducted from the tank 20 to a first valve 24 and from there to a water outlet 25 for connection to a container 2 with NaCl powder via said conduit 10. Saturated NaCl solution is returned from the container 2 via said conduit 11 to a concentrate inlet 27 which leads to a second valve 29. A second container 3 is connected between a water outlet 26 associated with the first valve 24 and a concentrate inlet 28 which is connected to the second valve 29. It will be apparent that by switching the valves 24 and 29, the first container 2 or the second container 3 are alternatively connected to the concentrate generator 1. It will further be apparent that more than two containers can be connected in parallel if so desired by arranging more water outlets and concentrate inlets to the valves 24 and 29 respectively. Whilst one of the containers is connected, the other can be exchanged and prepared for use, in which manner continuous supply can be assured.

The concentrate flows from the second valve 29 via a pressure meter 30, a pump 31, a conductivity meter 32 and a third valve 33 to the concentrate outlet 5 for further transport to the distribution conduit 6 and the concentrate connectors 8, and back to the return inlet 7.

From the return inlet 7, the returned concentrate is fed via a fourth valve 36 back to a mixing point 34 upstream of the pump 31 for recirculation in the distribution conduit 6. The third valve 33 is arranged to direct the concentrate to a drain 35 if the conductivity meter 32 provides a value which does not lie within a predetermined range corresponding substantially to concentrated sodium chloride solution. It will be apparent that other types of meter other than conductivity meters can be used, such as ion-selective meters, etc.

The above-mentioned meters 30, 32 and devices 33, 34, 36 are not completely necessary for the system (with the possible exception of the pump 31), but the use of these devices does increase safety. It is to be noted that corresponding safety features are normally provided in the dialysis machine.

It should be mentioned that it is not necessary to recirculate the saturated concentrate, but instead the return inlet 7 and the recirculation can be omitted in cer-

tain applications. Furthermore, it is not always necessary to have the tank 20 for water; instead the water can be fed directly to the containers 2, 3. The water tank 20 can also be smaller in size and in principle may only contain the heating source 23 for on-line heating of the incoming water. Thus, the expression water tank includes all different sizes from, in principle, merely a widening of a conduit to larger storage tanks.

The containers 2, 3 contain sodium chloride in powder form in a large bag or sack. One embodiment of the bag is shown in more detail in Fig. 3 and consists of a six-sided inner bag 40 made from polyethylene or polypropylene or similar material. The inner bag can be totally or partially stiff or self-supporting so that it adopts the shown shape, or alternatively can be flexible.

An inlet 41 for water for connection to the conduit 10 is provided at the upper end of the bag. In addition, a particle filter 42 and an outlet 43 in the form of a tube 44 are provided at the lower end of the bag, the tube opening out into a connector 45 which forms the outlet for saturated concentrate. The tube 44 and the connector 45 correspond to the conduit 11 in Fig. 1.

The connector 45 and the inlet 41 are differently shaped, such as male and female connectors respectively, to avoid incorrect coupling. Furthermore, the connector 45 can be directly connected to the inlet 41 to seal the bag during transport or when the bag is not in use.

It is also possible to connect several bags in series to extend the operating time. Since water is supplied to the first of the series-connected bags, the powder in the first bag will be consumed first, whereafter the powder in the next bag will be consumed. Since concentrate is removed from the last bag of the seriesconnected bags, the powder in all the series-connected bags will be consumed successively.

At least the lower region 46 of the bag is conical, which facilitates the utilization of all the sodium chloride in the bag.

The inner bag is housed in a protective casing 50 as shown in Fig. 4. The casing is manufactured from cardboard or hard plastic or similar material. The casing 50 is shown in Fig. 4 with the inner bag arranged therein. As is apparent from Fig. 4, an upper chamber 51 is created above the inner bag in which the tube 44 and the connector 45 can be accommodated and placed during transport.

The casing can be made from a blank which is shown in detail in a flat condition in Fig. 5 and in an erect condition in Fig. 6. Suitably, handles 52 are stamped out in the side. Alternatively, carrying means such as straps can be provided to facilitate transport.

The inner bag 40 is filled by the manufacturer with sodium chloride in powder form and is then transported to the user who may be a dialysis clinic, etc. The shape of the casing is so chosen that it can be easily transported by conventional means, for example on load pallets of standard size 800 x 1200 mm.

It is already known per se to use common salt, NaCl, in cartridges and to allow water to flow through the car-

tridge and dissolve the common salt on-line according to requirements. In the above-mentioned EP-B1-0 278 100, a cartridge is described containing about 1000 g common salt, where it has been determined that a particle size between about 50  $\mu\text{m}$  and 200  $\mu\text{m}$  is suitable.

It has surprisingly been shown that such a cartridge can be made very large without the risk of lump formation of the common salt during operation with the granule sizes which are mentioned above. According to the present invention, this discovery is used to produce "cartridges" in the order of tens of kilograms in weight for central preparation of NaCl concentrate "on-line", whereby the common salt is dissolved during use. In this manner, batchwise preparation of the NaCl concentrate in large mixing vessels having a volume of tens of cubic meters is avoided.

By using common salt bags of this size, transport of large quantities of water which was previously required is avoided, thereby leading to large savings. Furthermore, large quantities of salt can be transported in one and the same bag and prepared on-line in a central system according to the present invention. No reloading is thus necessary; instead the container can be used in the form in which it arrives at the clinic.

The preparation takes place by supplying water, preferably purified water, to the common salt in powder form in the container or the inner bag. Water is supplied in such a quantity that the water level in the bag is above or level with the level of the common salt in the bag, which need not be all the way up to the upper end of the bag.

When the water is supplied to the powder, a mass of common salt particles is created which can move around each other in a manner similar to small stones in water. The particles are continuously dissolved so that the water becomes saturated with common salt. Thereafter, no further continued dissolving takes place; instead the saturated common salt solution and the common salt particles are in equilibrium.

When concentrate is removed via the conduit 11, the same quantity of water is supplied via the conduit 10 and the common salt is dissolved anew, so that the incoming water becomes saturated with common salt. Thus, the common salt particles are consumed continuously during withdrawal of concentrate. In between, no consumption of common salt particles takes place since the solution is saturated. Agglomeration is avoided, as mentioned above, by the selection of the particle size of the common salt particles. As soon as the NaCl powder is completely wetted, a mass or slurry of common salt powder and water is formed which exhibits no tendency to lump together but instead remains as a shapeless mass, with the common salt powder in solid form and water substantially saturated with dissolved common salt.

In order to take full advantage of the invention, it is suitable that the inner bag be so big that it provides advantages from a transportation point of view, etc. Accordingly, it is preferred that the bag contains at least about 10 kg salt and preferably more than about 20 kg salt. A preferred size is about 40 kg, above which size

the bag can become difficult to handle. Bags of around 65 kg and up to about 100 kg can still be possible.

As mentioned above, saturated NaCl solution is a very poor growth medium for bacteria. Despite this fact, the distribution conduits 6 and the concentrate connectors 8 still must be disinfected at regular intervals.

For this purpose, another positive property of NaCl solution, namely that the solubility is substantially temperature independent, is exploited. It is therefore possible to heat saturated NaCl solution to a high temperature suitable for disinfecting without the risk of precipitation or crystal formation or that the properties of the concentrate be changed. Accordingly, the conduits 6 and the connectors 8 can be disinfected by the concentrate itself without having to first flush them clean of concentrate.

During disinfecting, the fourth valve 36 is first switched to a disinfecting position for recirculation of the concentrate to the water tank 20.

A bypass conduit 37 between the first valve 24 and the second valve 29 bypasses the containers 2 and 3 since the plastic material in the containers would otherwise be liable to be damaged by the high temperature and the time for the heating up would also be extended. In this manner, the entire concentrate generator including the water tank 20 is filled with concentrate. Alternatively, the water in the water tank 20 can be used to dilute the concentrate in the conduit 6 so that this solution which is used for disinfecting is not totally saturated. Of course, also only water or water including only a small portion of salt can alternatively be used.

The heating source 23 is now activated to gradually heat the concentrate to such a temperature that disinfecting takes place, for example a temperature above 90°C, preferably about 98°C or up to 105°C, and the circulation is allowed to continue for a suitable period of time, for example at least 30 minutes. Thereafter, the system is allowed to cool and the valves are switched to normal operation.

If the system is closed, even higher temperatures can be used, for example 121°C, at which sterilization is achieved. In this manner, an overpressure of about one atmosphere is attained in the system.

The above-described disinfecting can be executed entirely automatically, for example at night, when the dialysis clinic is not normally in operation.

It is possible to operate the concentrate generator 1 at a continuously high temperature, whereby disinfecting is achieved during operation. For reasons of safety, it can be suitable to maintain this temperature at about 60°C, but it is also possible to use temperatures in the order of just over 90°C. In the latter case, it should be ensured that the connectors to the dialysis machine have safety means so that scalding cannot occur.

As an alternative or complement to the particular bypass conduit 37, the conduit 10 can be disconnected from the container 2 and connected directly to the corresponding concentrate inlet 27 so that the concentrate can flow along this path during disinfecting.

It will be appreciated that disinfecting agents other than saturated common salt concentrate can be used in the system according to the invention.

It can be suitable to fill the common salt containers 2, 3 with water at the same time that they are connected to the concentrate generator 1 according to the invention, so-called priming. The reasons for this are many, such as that the common salt powder should be moistened before use and flushing out particles which may have lodged in the tubes or the connectors. During this priming, the third valve 33 is set so that the concentrate is fed to the outlet 35, and the pump 31 pumps water from the tank 20, through the tubes 10 and 11 to the drain. After a short period and when the conductivity meter 32 provides correct measured values, the priming is discontinued by switching the third valve 33 to its normal position.

Priming of one container can take place whilst the other is in use. Necessary valves and conduits for this purpose are not shown, though these are evident for a skilled person. Moreover, separate pumps and conductivity cells can be arranged for each container to facilitate simultaneous priming. This also applies for means for emptying the entire concentrate generator.

In Figs. 1 and 2, two containers 2 and 3 are shown connected in parallel. It will be apparent that the second container can be connected when the first container is empty so that a longer operating time can be achieved, which occurs with the valves 24 and 29. An indication that the one container is empty is thus obtained by means of the conductivity meter 32. Alternatively, the pressure meter 30 can be used which indicates a lower pressure as the container is emptied, or visual indication on the NaCl containers. Further pressure meters can be placed in other positions in the system, for example in the outlets 25, 26 for controlling the filling of each container.

The containers and the system are particularly suitable for preparation of saturated common salt solution for use in haemodialysis, haemofiltration or haemodiafiltration. Remaining constituents of the dialysis solution are prepared by the monitor, such as bicarbonate solution via a BICART® cartridge, and remaining electrolytes via a bag containing such electrolytes in concentrated dissolved form, for example in a concentration of 1:400. These electrolytes can be potassium chloride, calcium chloride, magnesium chloride and possibly glucose. In addition, acetic acid is normally added to adjust the pH value to 7,2 - 7,4 in the final dialysis solution.

The composition of the prepared dialysis solution is determined by the dialysis machine. The concentration of the substantially saturated common salt solution is measured by the dialysis machine and the measured value controls a pump or valve so that the correct quantity of common salt is mixed in the dialysis solution.

Salts other than common salt can also be prepared centrally according to the invention. One such salt is potassium chloride which has substantially the same properties as common salt. However, such small quantities of potassium chloride are used in the dialysis solu-

tion that the economic benefits of central preparation of potassium chloride concentrate rarely justifies such an investment. Those salts which can be prepared according to the invention should be such salts in which bacteria growth is minimal.

It is possible to prepare several salts in parallel and to distribute these concentrates in separate parallel distribution conduits to the dialysis machine. It is to be noted that with the invention two parallel distribution conduits are used, one for the concentrate according to the invention and one for purified water which must also be supplied to the dialysis machine.

It can also be possible to mix two of the ingredients already during the central preparation of the concentrate according to the invention. Normally, however, only one salt is included in the concentrate because of the difficulty of dosing the concentrate in the dialysis machine and achieving the correct composition. It can however be possible to add an acid to the water tank 20. The acid can be acetic acid and is used in dialysis solution to adjust the pH value to avoid precipitation of calcium carbonate and other such impurities.

It is to be noted that the expression water which is used above can also include water with certain additions, such as acid, etc. In addition, this water can, for example after a disinfection treatment, contain common salt or other electrolytes.

It can also be possible to dilute the common salt concentrate so that it is not saturated when it is fed to the distribution conduit 6. In this manner, the use of two parallel distribution conduits can be avoided, one for the common salt concentrate and the other for water; instead these can be combined in one and the same distribution conduit. In this manner, it is necessary that the solution which is fed to the distribution conduit has the lowest expected concentration for sodium and a final adjustment of this concentration is made in the dialysis machine according to individual requirements. In this embodiment, carbon dioxide gas can be added to the mixture of water and NaCl, whereby a sufficient quantity of carbon dioxide can dissolve in the mixture so that necessarily low pH values are obtained in the prepared dialysis solution without additional mixing of carbon dioxide or other acids. Since the solubility of carbon dioxide in water is proportional to the pressure, additional quantities of carbon dioxide can be dissolved if the concentrate generator is operated at an overpressure of, for example, about one atmosphere.

During disinfection, it can be suitable to use saturated common salt concentrate to obtain as efficient a disinfection as possible, particularly with regard to the fact that saturated common salt concentrate can be heated to about 107°C before it boils.

A plurality of distribution conduits 6 which are connected in parallel or in series can be used.

It is preferred to remove the substantially saturated concentrate from the lower portion of the container. It is also possible to remove the concentrate from the upper portion of the container or some other intermediate posi-

tion. It is to be noted that the common salt solution may stratify, particularly when the container contains smaller quantities of common salt in solid form at the end of the container's use. When removing concentrate from the upper portion of the container, the concentrate can thus have a lower concentration than that when it is saturated. Even though common salt has high solubility and dissolves quickly in water, under certain operating conditions with high flow velocity of water through the container it may occur that the removed concentrate is not saturated. The expression "substantially saturated concentrate" is intended to include these departures from the concentrated condition, either permanently, for example because of stratification, or constant high flow velocity, or temporarily because of deviations which can exceptionally arise, such as at the end of the use of a container. Normally, monitoring takes place to ensure that the concentrate is sufficiently concentrated or saturated by means of the conductivity meter 32. If concentrate with too low concentration should reach a dialysis machine, this will emit an alarm signal to indicate that sufficient final concentration in the dialysis solution cannot be attained.

The invention has been described in the above with reference to a preferred embodiment of the invention. However, it is to be understood that the invention can be modified in many ways by a skilled person reading this description, and the intention is that such modifications which are evident to a skilled person are to be included within the scope of the invention. The various described components can be combined in other ways than those shown in the drawings. The invention is limited only by the appended claims.

#### Claims

1. Method for centrally preparing and distributing a concentrate of substantially only one salt in water for preparation of a medical solution starting from the concentrate, for example dialysis solution and/or replacement solution for haemodialysis, haemofiltration or haemodiafiltration, **characterized by**
  - supplying primarily water to a container containing the salt at least partially in solid form,
  - removing substantially saturated concentrate of the salt in water from the container,
  - distributing the concentrate to a distribution conduit and concentrate connectors arranged thereon, for preparation of the medical solution.
2. Method according to claim 1, **characterized by** heating the concentrate and/or water to a high temperature for distribution of the concentrate at said temperature to the distribution conduit.
3. Method according to claim 1 or 2, **characterized by** adding a substance such as acetic acid to the concentrate or the water.
4. Method according to claim 1 or 2, **characterized by** diluting the concentrate to a suitable concentration for the dialysis solution, and adding carbon dioxide gas before the distribution to the distribution conduit.
5. Method according to any one of the previous claims, **characterized in that** the distribution takes place at overpressure.
6. Arrangement for centrally preparing and distributing a concentrate of substantially only one salt in water, for preparing a medical solution starting from the concentrate, for example dialysis solution and/or replacement solution for haemodialysis, haemofiltration or haemodiafiltration, comprising a concentrate generator (1) provided with an inlet (4) for water and at least one distribution conduit (6) for distribution of the concentrate to at least one concentrate connector (8), **characterized by**
  - at least one container (2, 3) for said salt which is at least partially in solid form;
  - a conduit (10) for supplying primarily water to the container (2, 3) to form a substantially saturated concentrate of the salt in water in the container (2, 3) by partial dissolving of the salt in the water; and
  - a conduit (11) for feeding the concentrate to the distribution conduit (6).
7. Arrangement according to claim 6, **characterized in that** the container (2, 3) contains the salt in a quantity of at least 10 kg, preferably more than 20 kg and most preferably more than 40 kg.
8. Arrangement according to claim 6 or 7, **characterized in that** the salt is sodium chloride in particle form, which particles have a size between about 50 and 200  $\mu\text{m}$ .
9. Arrangement according to any one of claims 6-8, **characterized in that** the concentrate generator (1) includes:
  - a water tank (20) to which primarily water is introduced via an inlet (4),
  - a conduit (10) for supplying water from the water tank (20) to one of the containers (2, 3);
  - a return conduit (11) for returning substantially saturated concentrate from the container (2, 3) to the concentrate generator (1); and
  - a pump (31) for feeding the concentrate solution to the distribution conduit (6).
10. Arrangement according to claim 9, **characterized by** a pressure meter (30) arranged in association with the inlet to the pump (31) to detect a pressure downstream of the container (2, 3), and a concentration meter (32) to measure the concentration of the salt in the concentrate before it is fed to the distribution conduit (6), and a valve (33) for directing the concentrate to a drain (35) should an error arise.



11. Arrangement according to any one of claims 6-10, characterized by a metering arrangement for adding a substance to the concentrate or the water in the concentrate generator (1), such as an acid, particularly acetic acid or carbon dioxide gas. 5
12. Method for disinfecting an arrangement intended for central preparation and distribution of a concentrate of substantially one salt in water, and consisting of a concentrate generator (1) and at least one distribution conduit (6) for distribution of the concentrate to at least one concentrate connector (8), characterized in that the concentrate is recirculated in a recirculation circuit comprising at least the distribution conduit (6), and in that the concentrate is heated to a high temperature, and possibly at an overpressure, to attain disinfection of the recirculation circuit. 10 15
13. Container suitable for the arrangement according to any one of claims 6-11, characterized in that it contains sodium chloride in particle form in a quantity of at least 10 kg, preferably more than 20 kg and most preferably more than 40 kg, and in that it is provided with an inlet (41) for water and an outlet (43, 44, 45) for concentrate, which inlet and outlets preferably have different connecting means, for example of male and female type. 20 25

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Fig.1

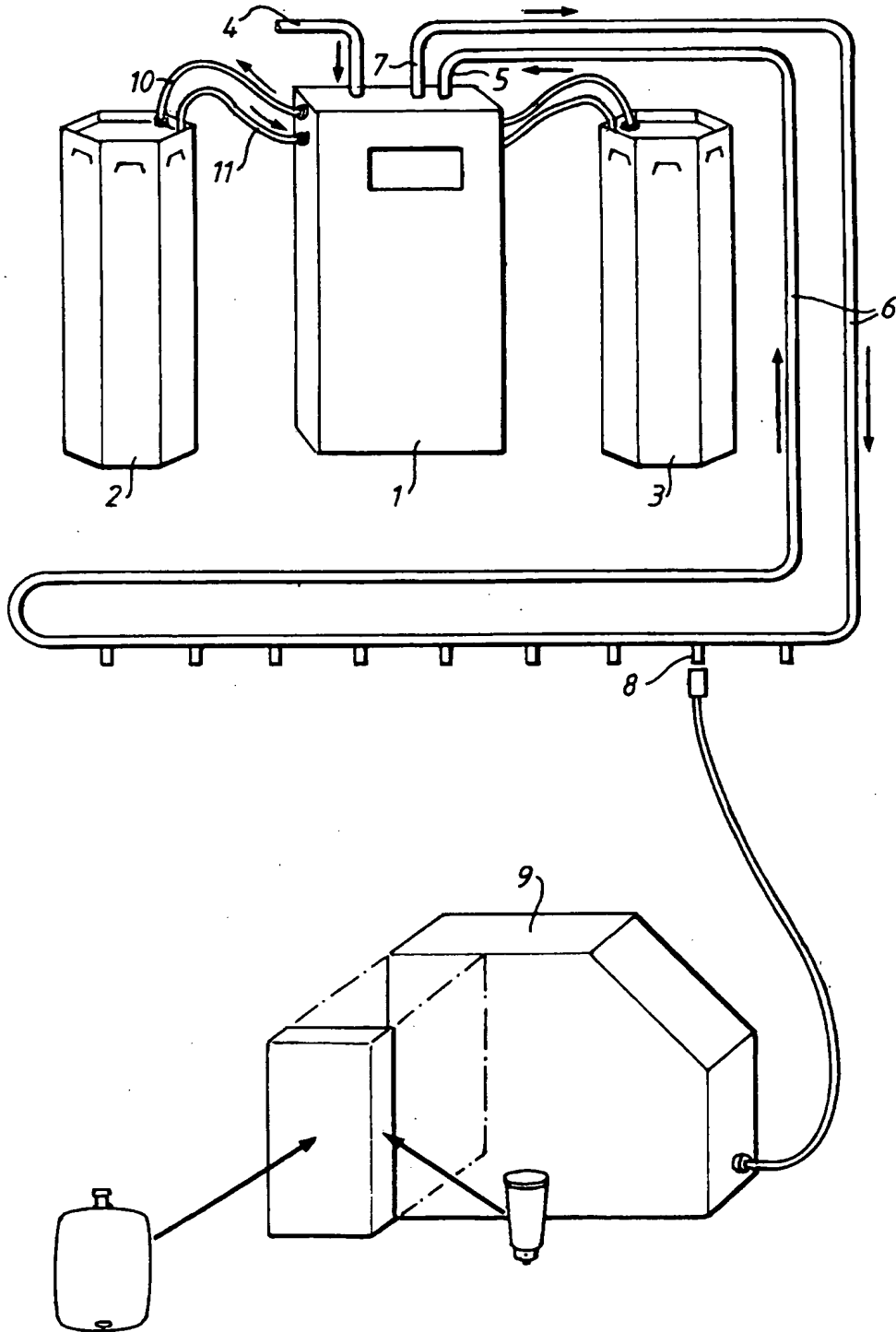


Fig. 2

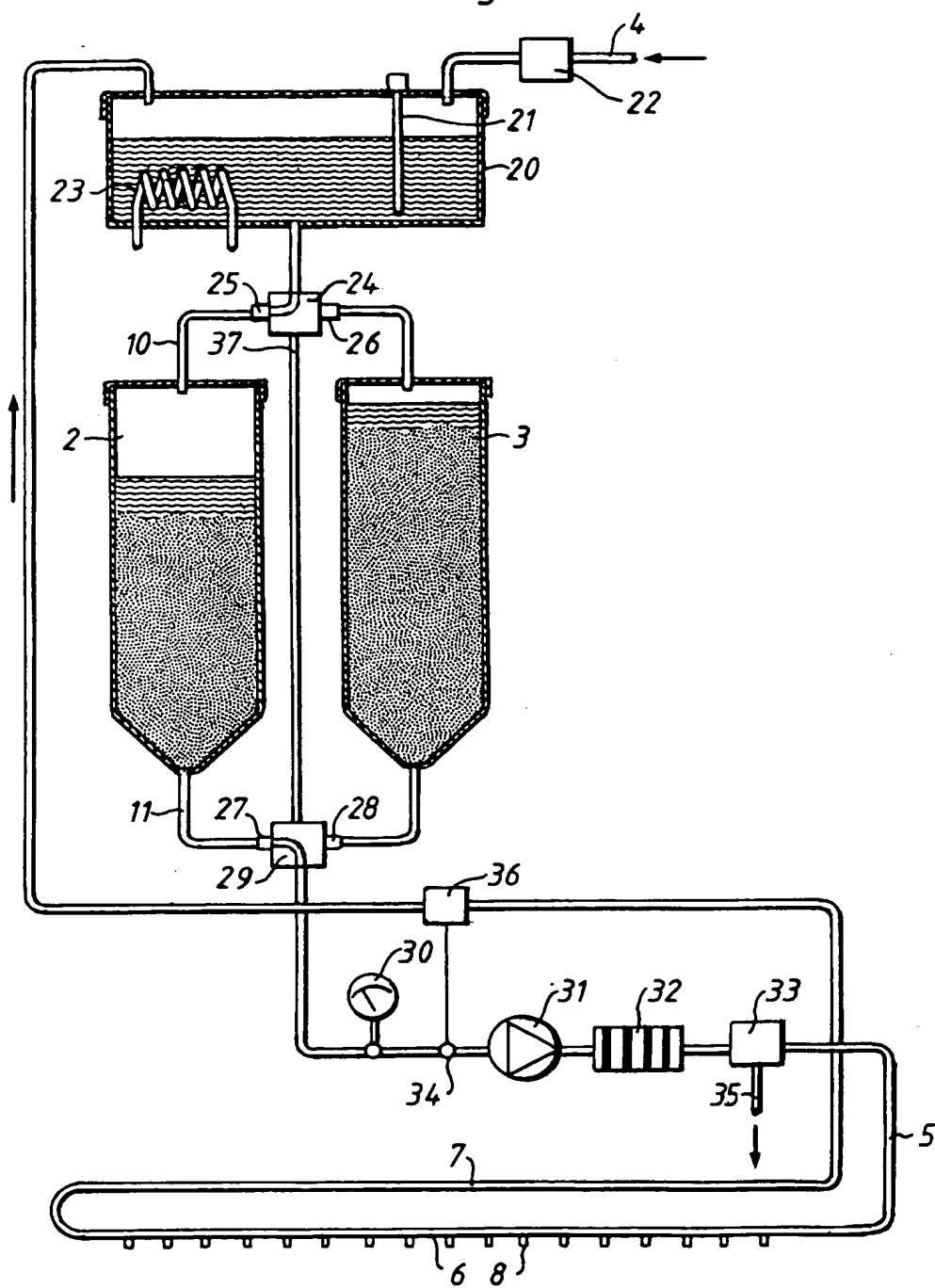


Fig. 3

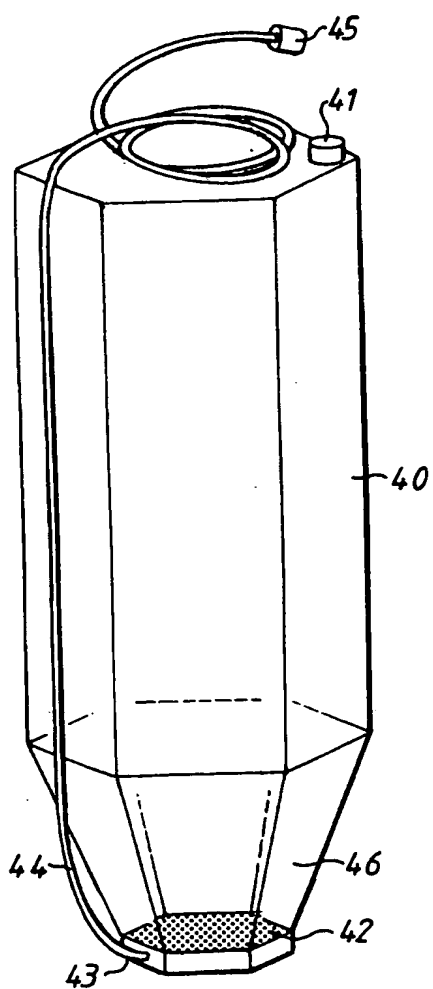
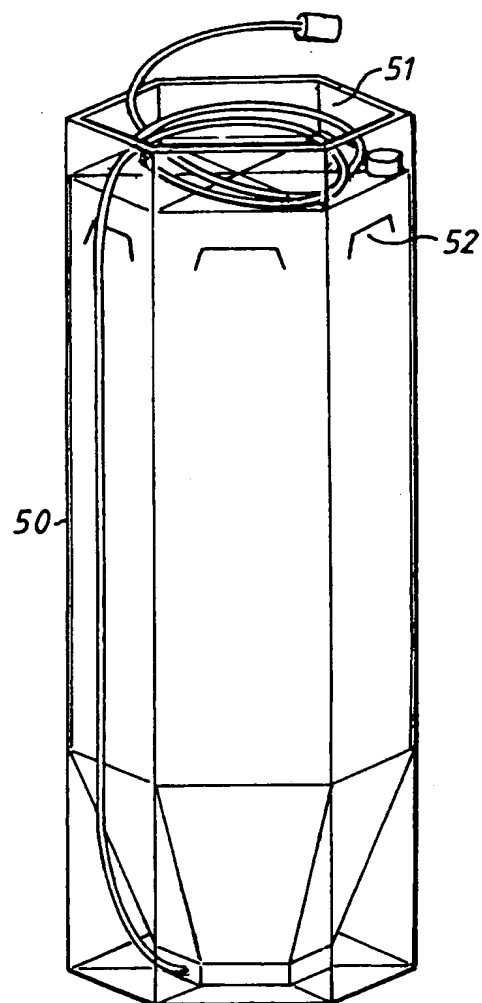
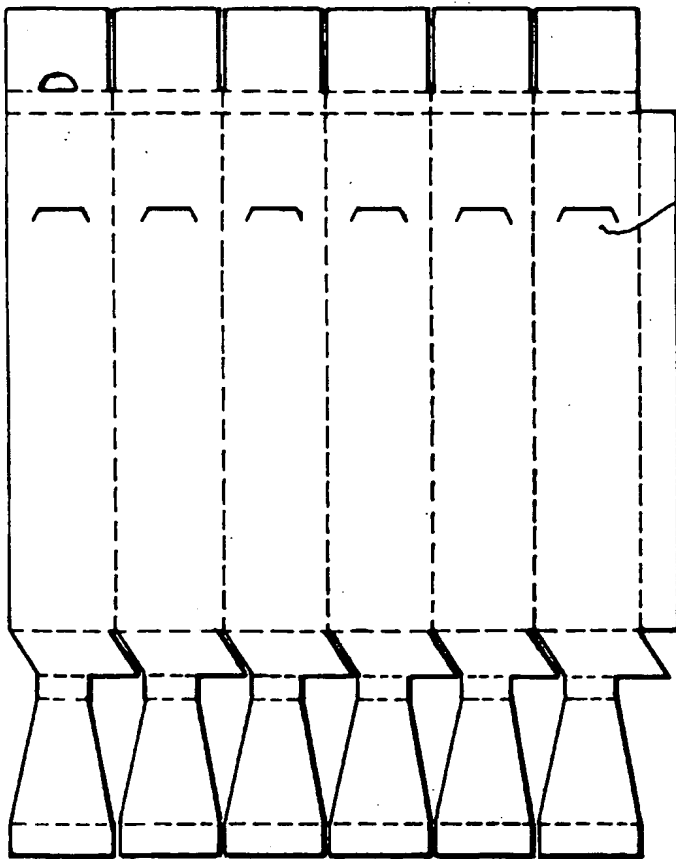


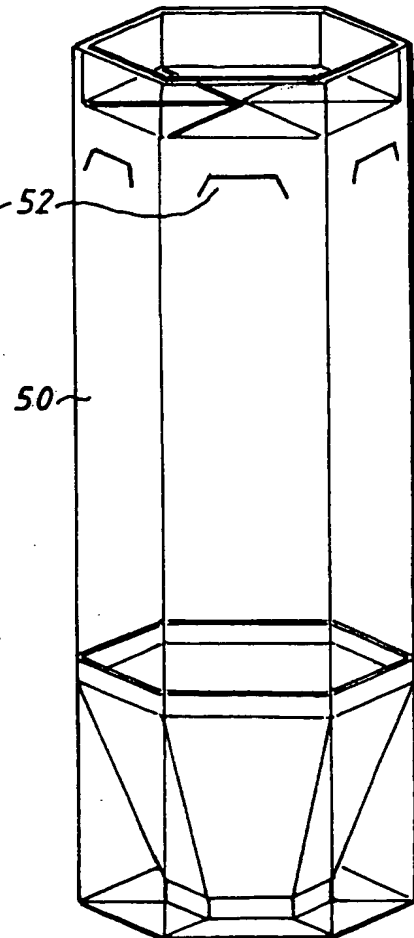
Fig. 4



*Fig. 5*



*Fig. 6*





European Patent  
Office

# EUROPEAN SEARCH REPORT

Application Number  
EP 95 11 4362.7  
Page 1

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.6)
X	EP, A1, 0401130 (HOSPAL INDUSTRIE), 5 December 1990 (05.12.90) * column 1, line 1 - line 6; column 1, line 30 - line 44; column 1, line 50 - column 2, line 2, column 5, line 13 - line 18, figure 2 *	1-3, 5-8,10, 11	A61M 1/14 A61K 9/08 A61K 9/14 B01F 1/00 A61L 2/04
Y	* column 3, line 13 - line 20 *  --	4	
Y	EP, A1, 0209607 (DIETL, HANS), 28 January 1987 (28.01.87) * figure 1, claim 1 *  --	4	
A	EP, A1, 0208090 (GAMBRO AB), 14 January 1987 (14.01.87) * figure 1, claim 1 *  --	12	
A	EP, A1, 0458041 (GAMBRO AB), 27 November 1991 (27.11.91) * figure 1, claim 1 *  --	12	TECHNICAL FIELDS SEARCHED (Int. Cl.6)  A61K A61L A61M B01F
A	EP, A2, 0439793 (GAMBRO AB), 7 August 1991 (07.08.91) * figure 1, abstract *  --	1,6	
The present search report has been drawn up for all claims			
Place of search STOCKHOLM		Date of completion of the search 18 December 1995	Examiner BENGT CHRISTENSSON
<p><b>CATEGORY OF CITED DOCUMENTS</b></p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons ..... &amp; : member of the same patent family, corresponding document</p>			

EPO FORM 1503 03.82 (P64/1)



European Patent  
Office

# EUROPEAN SEARCH REPORT

Application Number  
EP 95 11 4362.7  
Page 2

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.6)
A	EP, A2, 0278100 (GAMBRO AB), 17 August 1988 (17.08.88) * figure 1, claim 1 *	1,6	
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A	EP, A1, 0605395 (GAMBRO AB), 6 July 1994 (06.07.94) * figure 1, abstract *	1,6	
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A	EP, A1, 428009 (GAMBRO AB), 22 May 1991 (22.05.91) * claims 1,10 *	12	
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The present search report has been drawn up for all claims			
Place of search		Date of completion of the search	Examiner
STOCKHOLM		18 December 1995	BENGT CHRISTENSSON
<p><b>CATEGORY OF CITED DOCUMENTS</b></p> <p>X : particularly relevant if taken alone  Y : particularly relevant if combined with another document of the same category  A : technological background  O : non-written disclosure  P : intermediate document</p> <p>T : theory or principle underlying the invention  E : earlier patent document, but published on, or after the filing date  D : document cited in the application  L : document cited for other reasons  &amp; : member of the same patent family, corresponding document</p>			

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European Patent  
Office

EP 95114362.7

### CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

- ☐ All claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for all claims.
- ☐ Only part of the claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claims:
- ☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

### ☒ LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirement of unity of invention and relates to several inventions or groups of inventions, namely:

The subjects, defined by the problem and their means of solution, as listed below are so different from each other that no technical relationship or interaction can be appreciated to be present so as to form a single general inventive concept.

Claims 1-11 and 13 describe a method for preparing and distributing a concentrate of salt in water for preparation of a medical solution by supplying water to the salt, removing saturated concentrate of the salt and distributing the concentrate.

Claim 12 describes a method for disinfecting an arrangement intended for preparation and distribution of a concentrate of salt in water, and consisting of a concentrate generator and one distribution conduit by recirculating the concentrate and heating the concentrate.

- ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

- ☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.
- ☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:
- ☐ None of the further search fees has been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims: